



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1484]

Hung Yi Lin: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Hung Yi Lin for a period of 12 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Ms. Lin was convicted, as defined in the FD&C Act, of three felony counts under Federal law for conduct relating to the importation into the United States of an article of food. Ms. Lin was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of August 29, 2014 (30 days after receipt of the notice), Ms. Lin had not responded. Ms. Lin's failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division Of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr. (ELEM4144), Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On September 30, 2013, Ms. Lin was convicted, as defined in section 306(l)(1)(B) of the FD&C Act, when the U.S. District Court for the Northern District of Illinois accepted her plea of guilty and entered judgment against her for the following offense: Three counts of entry of goods into the United States by means of false statements, in violation of 18 U.S.C. 542.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for these convictions is as follows: Ms. Lin owned and operated KBB Express Inc., a freight forwarding company located in South El Monte, CA that provided nationwide transportation, delivery, and other logistical services for imported and entered merchandise, including Chinese-origin honey. Ms. Lin also served as the U.S. agent for at least 12 importers for which she handled the process of importing, and coordinating with brokers to enter and bring in, Chinese-origin honey into the United States.

On or about December 13, 2009, Ms. Lin entered and introduced Chinese-origin honey into the United States by means of a false and fraudulent practice, false statement, and fraudulent

and false papers, including Bureau of Customs and Border Protection (CBP) forms that falsely declared that approximately four container loads of Chinese-origin honey with a declared value upon entry of approximately \$92,822 was Chinese honey syrup. By so doing, Ms. Lin caused losses to the United States of approximately \$205,141 in uncollected anti-dumping duties and honey assessment fees, when in fact she knew the product was Chinese honey. This was in violation of 18 U.S.C. 542.

On or about December 13, 2009, Ms. Lin entered and introduced Chinese-origin honey into the United States by means of a false and fraudulent practice, false statement, and fraudulent and false papers, including CBP forms that falsely declared that approximately three container loads of Chinese-origin honey with a declared value upon entry of approximately \$69,617 was Chinese honey syrup. By so doing, Ms. Lin caused losses to the United States of approximately \$153,855 in uncollected anti-dumping duties and honey assessment fees, when in fact she knew the product was Chinese honey. This was in violation of 18 U.S.C. 542.

On or about December 13, 2009, Ms. Lin entered and introduced Chinese-origin honey into the United States by means of a false and fraudulent practice, false statement, and fraudulent and false papers, including CPB forms that falsely declared that approximately three container loads of Chinese-origin honey with a declared value upon entry of approximately \$69,617 was Chinese honey syrup. By so doing, Ms. Lin caused losses to the United States of approximately \$153,855 in uncollected anti-dumping duties and honey assessment fees, when in fact she knew the product was Chinese honey. This was in violation of 18 U.S.C. 542.

Ms. Lin admitted that between 2009 and 2012, she caused up to 764 shipping containers of Chinese-origin honey valued at approximately \$11,489,306 to be fraudulently imported and

entered into the United States, thereby causing losses to the United States of as much as \$39,203,144 through her fraudulent practices.

As a result of her conviction, on July 25, 2014, FDA sent Ms. Lin a notice by certified mail proposing to debar her for a period of 12 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Ms. Lin's felony convictions for entry of goods by means of false statements in violation of 18 U.S.C. 542 constitute conduct relating to the importation into the United States of an article of food because she committed an offense related to the importation of Chinese honey into the United States.

The proposal was also based on a determination, after consideration of the factors set forth in section 306(c)(3) of the FD&C Act, that Ms. Lin should be subject to a 12-year period of debarment. The proposal also offered Ms. Lin an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Lin failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Hung Yi Lin has been convicted of three felony counts under Federal law for conduct relating to the importation into the United States of an article of food and that she is subject to a 12-year period of debarment.

As a result of the foregoing finding, Hung Yi Lin is debarred for a period of 12 years from importing articles of food or offering such articles for import into the United States, effective (see DATES). Under section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Hung Yi Lin is a prohibited act.

Any application by Ms. Lin for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2013-N-1484 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.